

U.S. Food and Drug Administration
Drug Safety and Risk Management Advisory Committee
July 17, 2002

Materials attached:

1. Overview of patient information history at FDA
2. “Evaluation of Written Prescription Information Provided in Community Pharmacies, 2001: Final Report to the U.S. Department of Health and Human Services and the Food and Drug Administration”

FDA is seeking scientific discussion of and advice on the following questions:

1. What are the priority areas for improvement of useful consumer medication information?
2. Where in the process of development and distribution of written patient medication information might interventions improve the quality of information patients receive?
3. What kinds of intervention strategies could be helpful?
4. What are meaningful times to reevaluate consumer medication information before 2006?
5. What outcomes research can be implemented to assess how well the usefulness criteria serve to inform and guide the actions of patients?
6. How can outcomes research be used to establish priorities, if necessary, among criteria?

